HFE-35

U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

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Telephone: [718] 340-7000 [Ext 5301]

Warning Letter

Certified Mail
Return Receipt Requested

David L. Wuest, MD
Director of Blood Bank
Memorial Sloan Kettering Cancer Center
1275 York Avenue
New York, New York 10021

July 21, 1997

Ref.: 67-NYK-97

Dear Dr. Wuest:

During an inspection of Memorial Hospital for Cancer & Allied Diseases blood bank , located at 1275 York Avenue, New York, NY conducted between April 18 and May 20, 1997, our investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, (21 CFR), Parts 211 and 600-680.

At the conclusion of the inspection, the investigators presented their Inspectional Observations (FDA 483) to you and discussed their findings. The following violations were noted:

1. Failure to maintain complete and accurate records providing the entire history of all work performed.

a. Printout tapes containing unit testing results generated by the [redacted] are not always maintained. Batch plates were re-read without documenting the reason for invalidating the initial read, nor are the initial read tapes available. For example: HIV 1/HIV-2 assays, plate # 4468374, HTLV-1 assays, plate # 4841868, HCV assay, plate # 5871983, HIV-1 assays, plate # 5871296, HBC assays, plate # 5870693, CMV assays, plate # 4467950, and HBsAg assays, plate # 5870870.

b. Failure to document post transfusion ABO and Rh results performed on the blood unit investigated for transfusion reaction.

2. Failure to maintain and/or follow adequate written standard operating procedures.

a. Failure to maintain a written standard operating procedure for the re-reading of viral test assays.

b. The standard operating procedure for the quality control of platelets was not

followed, nor was there a corrective action procedure for platelet yields which are out of range.

c. Failure to maintain a written standard operating procedure for the training of technicians and supervisors.

d. Failure to follow the standard operating procedure for the calibration of the Quantum II spectrophotometer.

e. Failure to maintain a written standard operating procedure addressing security access to critical functions on the [redacted] testing equipment.

f. Failure to maintain a written standard operating procedure for the maintenance of the water system used in testing with the [redacted] system.

3. Failure to maintain written validation protocol and procedures for software and hardware maintenance for the [redacted] computer system version [redacted]

4. Failure to have documented validation for the [redacted] software and the [redacted] software.

5. Failure to have documented maintenance checks for the [redacted] consistent with manufacturer's instructions for all scheduled checks for linearity and drift, for wipe down track and wash volume, and for cleaning the water canister and the fan filter.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. You are responsible for investigating and determining the causes of the violations and taking whatever action you deem necessary to correct these deviations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

We acknowledge that you have submitted to this office a response (your letter of May 23, 1997) to the Inspectional Observations which were issued at the end of the inspection. Your response outlines a number of actions taken or to be undertaken to correct the violations. A follow-up inspection will be required, however, to assure that the corrections are adequate and have been implemented.

We have reviewed your response and have the following comments relating to several of the observations:

Observations # 1-3. It appeared to our investigators that the first time the blood bank supervisor became aware of the re-reads was during the inspection. Our investigators also observed that the header and trailers of the tape printed by the reader were physically cut off, thus removing a record indicating that re-reads have occurred. These observations, and the lack of documentation for the reason for the re-reads, raise concern about the reliability of the

testing conducted on the units involved.

Observation #4. Your new and revised procedures must include adequate monitoring of testing procedures. Your quality assurance program must encompass appropriate standards for personnel, procedures, equipment, and record keeping to ensure product quality. We acknowledge your new standard operating procedure, and a future inspection will be conducted to assess its adequacy and implementation. Your new SOP should also include the instruction that initial and re-read tapes should not be altered.

Observation #7. Your new SOP regarding control of platelets should expand upon what an investigation should encompass and should clarify what corrective action is necessary when yields are out of specification.

Observation #9. Written training procedures should be established for supervisors as well as technologists.

Observation #12. Security controls should be established in writing. They should address the automated test system, as well as the blood bank computer system.

Your reply to this letter should be sent, within 15 days of the receipt of this letter, to the Food and Drug Administration, New York District, 850 Third Avenue, Brooklyn, NY 11232, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,

Brenda J. Holman
District Director

cc: Paul Marks MD
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